



Food and Drug Administration
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December 18, 2014

Ever Light Plastic Products Company, Ltd.
C/O Ms. Kathy Liu
Project Manager
Hongray USA Medical Products, Inc.
3973 Schaefer Avenue
Chino, CA 91710

Re: K142570

Trade/Device Name: Powder Free Vinyl Patient Examination Gloves
(Yellow, White, Blue, Pink)

Regulation Number: 21 CFR 880.6250

Regulation Name: Patient Examination Glove

Regulatory Class: I

Product Code: LYZ

Dated: October 22, 2014

Received: October 28, 2014

Dear Ms. Liu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K142570

Device Name

Powder Free Vinyl Patient Examination Gloves (Yellow, White, Blue, Pink)

Indications for Use (Describe)

A patient examination glove is disposable non-sterile device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Type of Use (Select one or both, as applicable)

☐ Prescription Use (Part 21 CFR 801 Subpart D)

☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Ever Light Plastic Products Co., Ltd.

Donggao Industrial Zone Zanzhuang, Shijiazhuang, Hebei, China 050000

Product: Powder Free Vinyl Patient Examination Gloves (Yellow, White, Blue, Pink)

510(K) SUMMARY

This summary of 510(K) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR §807.92.

The assigned 510(K) number is: K142570

1. Owner's Identification :

Mr. Zhang Litao

Ever Light Plastic Products Co., Ltd.

Donggao Industrial Zone Zanzhuang, Shijiazhuang, Hebei, China 050000

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Fax: 86-311-83616934

Contact: Ms. Kathy Liu, Project Manager

Address: 3973 Schaefer Ave., Chino, CA 91710

Tel: 909-590-1611

Fax: 909-590-1511

Date Summary Prepared: September 9, 2014

2. Name of the Device:

Trade Name: Powder Free Vinyl Patient Examination Gloves (Yellow, White, Blue, Pink)

Common Name: Exam Gloves

Classification Name: Patient Examination Glove

Classification Regulation: 880.6250

Classification Panel: 880 General Hospital and Personal Use

Product Code: LYZ

Device Class: Class I

3. Predicate Device Information:

Hongze Plastic Technology Co., Ltd.

Powder Free Vinyl Patient Examination Gloves, (Yellow, White, Blue, Pink)
(K101135)

4. Device Description:

Powder Free Vinyl Patient Examination Gloves (Yellow, White, Blue, Pink) are Patient Examination Gloves, Disposable, single use only and non-sterile. The gloves are made of vinyl materials and are powder free. The physical and performance characteristics of the devices meet all requirements of ASTM D5250-06

Ever Light Plastic Products Co., Ltd.

Donggao Industrial Zone Zanzhuang, Shijiazhuang, Hebei, China 050000

Product: Powder Free Vinyl Patient Examination Gloves (Yellow, White, Blue, Pink)

(Reapproved 2011) Standard Specification For Poly(Vinyl Chloride) Gloves For Medical Application.

5. **Intended Use of the Device:**

A patient examination glove is disposable non-sterile device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

6. **Technological Characteristics and Substantial Equivalence:**

Ever Light Plastic Products Co., Ltd.'s Powder Free Vinyl Patient Examination Gloves (Yellow, White, Blue, Pink) is substantially equivalent in safety and effectiveness to the Hongze Plastic Technology Co., Ltd.'s Powder Free Vinyl Patient Examination Gloves, (Yellow, White, Blue, Pink) (K 101135). The subject device and predicate device use a similar plastic flexible barrier film to achieve a device for the intended use.

And the properties between the subject device and the predicate device are compared in the following table:

Characteristics	Standard	Device Performance		Result of comparison
		Predicate device	Subject Device	
Product Code	/	LYZ	LYZ	Similar
Intended Use	/	Predicate device is disposable non-sterile device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	Subject device is disposable non-sterile device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	Similar
Labeling	/	There are no special labeling claims and do not claim gloves as hypoallergenic on labels.	There are no special labeling claims and do not claim gloves as hypoallergenic on labels.	Similar
Device Materials	/	Vinyl	Vinyl	Similar
Color	/	Yellow White Blue Pink	Yellow White Blue Pink	Similar
Device tolerances and specifications & Performance Data:				

Ever Light Plastic Products Co., Ltd.

Donggao Industrial Zone Zanhuan, Shijiazhuang, Hebei, China 050000

Product: Powder Free Vinyl Patient Examination Gloves (Yellow, White, Blue, Pink)

Characteristics	Standard	Device Performance		Result of comparison
		Predicate device	Subject Device	
Tensile strength: before and after aging	ASTM D 5250-06 (2011)	Before aging: 14.3-17.6MPa After aging: 13.3-16.8Mpa	Before aging: 15.2-18.1Mpa After aging: 14.6-17.4Mpa	Similar
Ultimate elongation: before and after aging	ASTM D 5250-06 (2011)	Before aging: 380-429% After aging: 370-401%	Before aging: 390-470% After aging: 360-450%	Similar
Freedom from pinholes	ASTM D 5250-06 (2011)	G-I, AQL2.5 125 glove sampled and 1 piece leaks	G-I, AQL2.5 125 glove sampled and 0 piece leaks	Similar
Dimensions: Overall length, Width, Palm and Finger thickness	ASTM D 5250-06 (2011)	Length:245-246mm Width: S/86, M/96, L/106, XL/116 Palm Thickness: 0.08-0.10mm Finger Thickness: 0.10-0.11mm	Length:232-245mm Width: S/87, M/97, L/107, XL/118 Palm Thickness: 0.08-0.10mm Finger Thickness: 0.10-0.12mm	Similar
Residual powder	ASTM D 5250-06 (2011)	0.9mg/glove	0.16 mg/glove	Similar
Biocompatibility				
Primary skin irritation test	ISO 10993-10	Under conditions of the study, not an irritant	Under conditions of the study, not an irritant	Similar
Dermal sensitization assay	ISO 10993-10	Under conditions of the study, not an irritant	Under conditions of the study, not an irritant	Similar
Indications For Use	/	Predicate device is disposable non-sterile device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination	Subject device is disposable non-sterile device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and	Similar

Ever Light Plastic Products Co., Ltd.

Donggao Industrial Zone Zanhuang, Shijiazhuang, Hebei, China 050000

Product: Powder Free Vinyl Patient Examination Gloves (Yellow, White, Blue, Pink)

Characteristics	Standard	Device Performance		Result of comparison
		Predicate device	Subject Device	
		between patient and examiner.	examiner.	

Ever Light Plastic Products Co., Ltd.'s Powder Free Vinyl Patient Examination Gloves (Yellow, White, Blue, Pink) shares the same or comparable technology characteristics compared to the predicate device. The subject device performs according to the glove performance standards ASTM D5250-06(2011), biocompatibility requirement and FDA requirements and the labeling claims for the product. It performs as well as the legally marketed predicate device.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence is as Follows:

Testing Items	FDA-recognized Standard Requirements	Inspection Level and AQL	Actual Testing Results	Conclusion
Overall Length (mm)	230 for all sizes minimum	S-2, AQL4.0	S: 232-245mm M:233-241mm L:236-243mm XL: 234-242mm	Pass
Width (mm)	S: 85±5	S-2, AQL4.0	87-88 mm	Pass
	M: 95±5		97-98 mm	
	L: 105±5		107-108 mm	
	XL: 115±5		118-119 mm	
Palm Thickness (mm)	0.08mm minimum	S-2, AQL4.0	0.08mm	Pass
Finger Thickness (mm)	0.05mm minimum	S-2, AQL4.0	0.10-0.12mm	Pass
Tensile Strength (Mpa)				
Before aging	11Mpa minimum	S-2, AQL4.0	15.2-18.1Mpa	Pass
After aging	11Mpa minimum		14.6-17.4Mpa	Pass
Ultimate Elongation (%)				
Before aging	300% minimum	S-2, AQL4.0	390-470%	Pass
After aging	300% minimum		360-450%	Pass
Pinhole	2.5	G-I	125 glove sampled and 0 piece leaks, meet AQL2.5	Pass

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Product: Powder Free Vinyl Patient Examination Gloves (Yellow, White, Blue, Pink)

			requirements	
Residual Powder	Not more than 2mg per glove	N=5	0.16mg	Pass
(a) Primary Skin Irritation Test	Under conditions of the study, not an irritant		Under conditions of the study, not an irritant	
(b) Dermal Sensitization Study	Under conditions of the study, not an irritant		Under conditions of the study, not an irritant	

8. Discussion of Clinical Tests Performed:

Not Applicable – There is no hypoallergenic Claim. There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. The substantial equivalence of the device is supported by the non-clinical testing.

9. Labeling:

We do not claim our gloves as hypoallergenic on our labels.

10. Conclusions:

Ever Light Plastic Products Co., Ltd's Powder Free Vinyl Patient Examination Gloves (Yellow, White, Blue, Pink) conform fully to ASTM D 5250-06 (2011) standard as well as applicable 21 CFR references, and meets pinhole FDA requirements, biocompatibility requirements and labeling claims as shown by data discussed above. There are no safety/efficacy issues or new claims from the "substantial equivalence" products cited.

Drawn from the complete list of non-clinical tests, the device herein mentioned is as safe, as effective, and performs as well as the legally marketed predicate device.